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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/785,577

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Lung-Ji Chang

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10/03/2007

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EXAMINER

FALK, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

10/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/785,577

Applicant(s)

CHANG, LUNG-JI

Examiner

Anne-Marie Falk, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-20 and 29-50 is/are pending in the application.
- 4a) Of the above claim(s) 29-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/23/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The response filed July 12, 2007 has been entered. Applicants' election without traverse of Group I, Claims 17-20, is acknowledged. The elected invention is drawn to a tumor cell composition comprising a tumor cell modified to express a B7-2 protein and at least one additional immune modulator, or a functional fragment of said B7-2 protein or said immune modulator. Applicants further elected GM-CSF as the cytokine species for prosecution.

Claims 17-20 and 29-50 are pending in the instant application.

Claims 29-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in the replies filed on February 28, 2007 and July 12, 2007.

Accordingly, Claims 17-20 are examined herein.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite a functional fragment of a B7-2 protein or a functional fragment of an immune modulating protein. However, the specification does not provide a written description of functional fragments of a B7-2 protein or functional fragments of an immune modulating protein. The specification

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does not clearly define the intended scope of the phrase "functional fragment" and it is unclear what particular function is being referred to. In the absence of a clear definition, the phrase encompasses a wide variety of fragments and there is no requirement that any essential part of the reference molecule remain as part of the "functional fragment." In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only a single embodiment, i.e. the B7-2 protein or the full-length immune modulating protein, is described by its complete structure. Next then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. In this case, the specification does not describe functional fragments by other relevant identifying characteristics. Furthermore, there is no requirement that any essential part of the reference protein remain as part of the "functional fragment." This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of functional fragments as recited in the claims, at the time the application was filed. Thus, it is concluded that the written description requirement is not met for the claimed genus of functional fragments.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,548,068 (Schlom et al., priority to 6/7/95).

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The claims are directed to a tumor cell composition comprising a tumor cell modified to express a B7-2 protein and at least one additional immune modulator, or a functional fragment of said B7-2 or said immune modulator. Dependent claims further specify that the immune modulator is a cytokine and that the cytokine is GM-CSF.

Schlom et al. disclose and claim a tumor cell modified to express B7-2 and GM-CSF. See especially Claims 1, 4, and 5. Claim 1 is directed to a host cell infected with a recombinant vaccinia virus which has incorporated into the viral genome a gene or portion thereof encoding B7-2. The claim further specifies that the B7-2 gene is expressed. Claim 4 is directed to the host cell according to Claim 1 wherein the recombinant virus further comprises one or more genes or portion thereof encoding an immunostimulatory molecule selected from the group consisting of IL-2, ICAM-1, LFA-3, CD72, GM-CSF, TNF $\alpha$ , INF $\gamma$ , IL-12, IL-6 and combinations thereof. Claim 5 is directed to the host cell according to any one of Claims 1 to 4 "wherein the host cells is ...a tumor cell ..." Thus, the patent clearly discloses a tumor cell modified to express both B7-2 and GM-CSF, as instantly claimed.

Thus, the claimed invention is disclosed in the prior art.

### ***Conclusion***

No claims are allowable.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/  
Primary Examiner, Art Unit 1632